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REMARKS

Claims 3-6 and 11-14 have been amended to replace “comprising” with “is” in relation to reciting various specific cations. Claim 9 has been amended to replace “and one” with “and one,” as pointed out and requested by the Examiner. Claim 2 has been amended to correct a slight formal error. No new matter is introduced by these amendments.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 3-6, 9 and 11-14 have been rejected as indefinite, for containing the claim transition “comprising,” “which is open-ended and allows the claims to read on mixtures rather than specific compounds,” according to the Office Action (page 4). Applicants submit that the rejection is moot, based on amendments made to the claims.

Regarding the term “comprising,” applicants have amended each rejected claim to reflect the fact that “the cation is” a particular cation. This would allow the claims to read on specific compounds, and the Examiner is requested to reconsider and withdraw the rejection.

Applicants have also amended claim 9 to replace “and one” with “and one,” an error and a correction which was immediately apparent to one of ordinary skill. Applicants respectfully submit that the claims as presented herein are not indefinite.

Rejections Under 35 U.S.C. § 102(a) and 102(e) Over Sherman (U.S. Patent No. 6,713,495), Vijayaraghavan et al. (U.S. Patent Application No. 2003/0212274), Kamiyama et al. (U.S. Patent Application No. 2003/0181247) and Gustavsson et al. (U.S. Patent No. 6,207,188)

Claims 1-15 have been rejected as anticipated by Sherman, Vijayaraghavan et al., Kamiyama et al., and Gustavsson et al. Applicants respectfully traverse the rejections for the following reasons.

Sherman

Sherman discloses a magnesium salt of omeprazole. In some portions of the Sherman disclosure, Sherman states that magnesium omeprazole can be prepared with crystallinity under 67%, or under 25%. Example 3 of Sherman states that powder was examined which had crystallinity of under 25%. There is no X-ray diffraction data presented in Sherman.

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Applicants claim amorphous esomeprazole salts, and various aspects of such materials. Sherman does not mention or disclose or otherwise relate to salts of esomeprazole of any kind, either amorphous or otherwise. Thus, there is clearly no anticipation of any of applicants' claims by Sherman.

Vijayaraghavan et al.

Vijayaraghavan et al. discloses salts of amorphous omeprazole. The polymorphic characters of these salts are exemplified by presentation of X-ray diffraction data of the magnesium salt of omeprazole, showing an amorphous form of that material (Fig. 2).

Applicants claim amorphous esomeprazole salts, and various aspects of such materials. Vijayaraghavan et al. does not mention or disclose or otherwise relate to salts of esomeprazole of any kind, either amorphous or otherwise. Thus, there is clearly no anticipation of any of applicants' claims by Vijayaraghavan et al.

Kamiyama et al.

Kamiyama et al. discloses salts of a particular benzimidazole compound, namely (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]-methyl]sulfinyl]-1H-benzimidazole. This compound is neither omeprazole nor esomeprazole, as is apparent from inspection of the chemical names of the Kamiyama et al. compound and esomeprazole ((S)-5-methoxy-2-[[[4-methoxy-3,5-dimethyl-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole).

Applicants claim amorphous esomeprazole salts, and various aspects of such materials. Kamiyama et al. does not mention or disclose or otherwise relate to salts of esomeprazole of any kind, either amorphous or otherwise. Thus, there is clearly no anticipation of any of applicants' claims by Kamiyama et al.

Gustavsson et al.

Gustavsson et al. discloses the sodium salt of omeprazole. In particular, Gustavsson et al. discloses a particular crystalline form B of sodium omeprazole. There does not appear to be any specific disclosure of an amorphous form in Gustavsson et al.

Applicants claim amorphous esomeprazole salts, and various aspects of such materials. Gustavsson et al. does not mention or disclose or otherwise relate to salts of

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esomeprazole of any kind, either amorphous or otherwise. Thus, there is clearly no anticipation of any of applicants' claims by Gustavsson et al.

Summary of Anticipation

In summary, while Sherman, Vijayaraghavan et al. and Gustavsson et al. discuss omeprazole salts, with varying degrees of disclosure or suggestion of an amorphous form, none of these references mentions, or alludes to, esomeprazole at all. The fourth reference, Kamiyama et al., appears to have nothing at all to do with omeprazole or esomeprazole. The Examiner would appear to appreciate that fact, as nowhere in the section on anticipation (Office Action pages 2-3) does the Examiner assert that esomeprazole is disclosed in the cited references much less an amorphous form thereof. There is no anticipation of applicants' claimed subject matter, and applicants respectfully request reconsideration and withdrawal of the rejection on these grounds.

Rejection Under 35 U.S.C. § 103(a) Over Sherman (U.S. Patent No. 6,713,495), Vijayaraghavan et al. (U.S. Patent Application No. 2003/0212274), Kamiyama et al. (U.S. Patent Application No. 2003/0181247) and Gustavsson et al. (U.S. Patent No. 6,207,188) in view of Bohlin et al. (U.S. Patent No. 6,162,816) and Broeckx et al. (U.S. Patent Application No. 2004/0209918)

Claims 1-15 have been rejected as obvious over Sherman, Vijayaraghavan et al., Kamiyama et al., and Gustavsson et al. in view of Bohlin et al. and Broeckx et al. Applicants respectfully traverse the rejection for the following reasons.

As discussed above in relation to the 35 U.S.C. § 102(a) and 102(e) rejections, none of the cited references Sherman, Vijayaraghavan et al., Kamiyama et al., or Gustavsson et al. disclose or allude to esomeprazole.

Bohlin et al. discloses crystalline forms of esomeprazole in the neutral, that is, not the salt, form. This material may also be referred to as esomeprazole base. Moreover, Bohlin et al., although mentioning an amorphous form of esomeprazole base, does not express as preferred such an amorphous esomeprazole base.

Broeckx et al. discloses processes for preparing particular benzimidazole-type compounds, and does not disclose the particular preparation of esomeprazole. Thus, there is no disclosure of an amorphous esomeprazole salt.

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The Examiner apparently seeks to formulate a prima facie case of obviousness involving Bohlin et al. or Broeckx et al. and each of the references Sherman, Vijayaraghavan et al., Kamiyama et al. and Gustavsson et al. The last four references lack any disclosure of esomeprazole, and Bohlin et al. provides a neutral, solid state form of esomeprazole. There is no apparent motivation to combine the disclosure of Bohlin et al. with any of the disclosures of Sherman, Vijayaraghavan et al., Kamiyama et al. or Gustavsson et al. to arrive at applicants' presently claimed amorphous salts of esomeprazole. The Examiner has not identified any such motivation, merely stating "Bohlin et al. and Broeckx et al. teach that omeprazole is a racemic mixture that consists of two single enantiomers. Hence, the claimed isomer as well as its relative selectivity of properties *vis-à-vis* the racemate are suggested by the reference." (Office Action, page 4, emphasis added).

Applicants object to the proposition put forth of "hence, the claimed isomer ... [is] suggested by the reference." The Examiner appears to miss the point that what is claimed is the amorphous form of a salt of esomeprazole. Whether or not an isomer is suggested by a reference disclosing a racemate is not the issue before the Examiner.

The departure of subject matter from what is disclosed or suggested in the cited references is far more significant than what has been set forth in the Office Action. Applicants respectfully request that a full discussion of the Examiner's view on motivation to combine the cited references be set to paper in the next Office Action. Applicants respectfully submit that the claimed subject matter is not obvious in light of the cited references.

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CONCLUSION

Applicants submit that all outstanding rejections have been overcome or mooted, and a Notice of Allowance is respectfully requested at this time.

Authorization is hereby given to charge any fees deemed to be due in connection with this Amendment and Response to Office Action to Deposit Account No. 50-0912.

Respectfully submitted,

By: _____


George E. Heibel, Esq.
Reg. No. 42,648

Ranbaxy Inc.
600 College Road East, Suite 2100
Princeton, New Jersey
Telephone (609) 720-5608
Facsimile: (609) 514-9779